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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/825,489	AGRAWAL ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 10-16, 19,20, 49, drawn to a method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to XPA gene, classified in class 514, subclass 44.

II. Claims 1-5, 17,19,20,49, drawn to a method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to XPG gene, classified in class 514, subclass 44.

III. Claims 1-5, 18-20, 49, drawn to a method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to CSA gene, classified in class 514, subclass 44.

IV. Claims 1-9, 19, 20, 49, drawn to a method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to CSB gene, classified in class 514, subclass 44.

V. Claims 21-25, 30-36, 39, 40, drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to XPA gene, classified in class 514, subclass 44.

VI. Claims 21-25, 37, 39, 40, drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to XPG gene, classified in class 514, subclass 44.

VII. Claims 21-25, 38-40, drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to CSA gene, classified in class 514, subclass 44.

VIII. Claims 21-29, 39, 40, drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to CSB gene, classified in class 514, subclass 44.

IX. Claims 41-44, drawn to a method of reducing the proliferation rate of a carcinoma cell using an oligonucleotide complementary to CSB gene, classified in class 514, subclass 44.

X. Claims 45 and 46, drawn to an oligonucleotide complementary to XPA gene, classified in class 536, subclass 24.5.

XI. Claims 47 and 48, drawn to an oligonucleotide complementary to CSB, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II and III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention I is drawn to a method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to XPA gene, invention II is drawn to a method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to XPG gene, invention III is drawn to a

method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to CSA gene and invention IV is drawn to a method to potentiate or enhance the toxic effect of a cytotoxin using an oligonucleotide complementary to CSB gene. Each one of these inventions has a different mode of operation from all of the others, invention I operates against XPA gene, invention II operates against XPG gene, invention III operates against CSA gene and invention IV operates against CSB gene.

2. Inventions V and VI and VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention V is drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to XPA gene, invention VI is drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to XPG gene, invention VII is drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to CSA gene and invention VIII is drawn to a method of sensitizing a resistant cell to a cytotoxin or oxidizing agent using an oligonucleotide complementary to CSB gene. Each one of these inventions has a different mode of operation from all of the others, invention I operates against XPA gene, invention II operates against XPG gene, invention III operates against CSA gene and invention IV operates against CSB gene.

3. The inventions of Groups I-IV and the inventions of Groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I-IV are drawn to a method of potentiating or enhancing the toxic effect of a cytotoxin or oxidizing agent and while the inventions of groups V-VIII are drawn to a method of sensitizing resistant cells to a cytotoxin or oxidizing agent. The methods have different functions by virtue of their being drawn to different types of cells.

4. The inventions of Groups I-IV and invention IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation; the inventions of groups I-IV operate by enhancing the toxic effect of a cytotoxin or oxidizing agent on a cell while invention IX operates by reducing the proliferation of a cancer cell with an oligonucleotide complementary to CSB gene.

5. The inventions of Groups I-IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions; the function of the inventions of groups I-IV is to enhance the toxic effects of a cytotoxin or oxidizing agent while the function of the oligonucleotide in invention X is to bind its complement, the XPA gene.

6. The inventions of Groups I-IV and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions; the function of the inventions of groups I-IV is to enhance the toxic effects of a cytotoxin or oxidizing agent while the function of the oligonucleotide in invention XI is to bind its complement, the CSB gene.

7. The inventions of Groups V-VIII and invention IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation; the inventions of Groups V-VIII operate by sensitizing a resistant cell to a cytotoxin or oxidizing agent while invention IX operates by reducing the proliferation of a cancer cell with an oligonucleotide complementary to CSB gene.

8. The inventions of Groups V-VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions; the function of the inventions of Groups V-VIII is to sensitize a resistant cell to a cytotoxin or oxidizing agent while the function of the oligonucleotide in invention X is to bind its complement, the XPA gene.

9. The inventions of Groups V-VIII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

MPEP § 808.01). In the instant case the different inventions have different functions; the function of the inventions of Groups V-VIII is to sensitize a resistant cell to a cytotoxin or oxidizing agent while the function of the oligonucleotide in invention XI is to bind its complement, the CSB gene.

10. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of reducing the proliferation rate of a carcinoma cell using an oligonucleotide complementary to CSB gene and an oligonucleotide complementary to an entirely different gene, namely XPA. There is no disclosure that states the oligonucleotide of invention X, XPA, would be capable of use in the method disclosed in invention IX that uses CSB gene.

11. Inventions IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide of invention XI could be used to bind with a sequence containing the CSB gene that was not in a cancer cell.

12. Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions are drawn to an oligonucleotide complementary to XPA gene and an oligonucleotide complementary to CSB gene. The oligonucleotide complementary to XPA would not have the same function as the oligonucleotide complementary to CSB; it would not be complementary to, and would not bind, CSB. Similarly, the oligonucleotide complementary to CSB would not have the same function as the oligonucleotide complementary to XPA for similar reasons.

13. Claims 1 and 21 are generic to a plurality of disclosed patentably distinct species, namely the cytotoxins and oxidizing agents comprising cisplatin, oxaliplatin, gamma radiation and hydrogen peroxide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. If any of groups I-VIII are elected, applicant must further elect one of the following species: cisplatin, oxaliplatin, gamma radiation or hydrogen peroxide.

Restriction to a single nucleotide sequence

16. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the antisense sequences listed in claims 1-49 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

17. Claims 8, 28, 43 and 47 specifically claim antisense SEQ ID NOS 1&2, which are targeted to CSB gene. Although the antisense sequences claimed each target the same gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed has a unique nucleotide sequence. Claims 12, 15, 32, 35 and 45 claim one or more of antisense SEQ ID NOS 3, 4 and 5, which are targeted to XPA gene. Although the antisense sequences claimed each target the same gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed has a unique nucleotide sequence. A search of more than one (1) of the antisense sequences in the above numbered claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) antisense sequence.

18. If group I or group V is elected, applicant must further elect one of the following sequences, Seq ID 3 or 4

19. If group IV or VIII is elected, applicant must further elect one of the following sequences, SEQ ID 1 or 2

20. If group IX is elected, applicant must further elect one of the following sequences, SEQ ID 1 or 2

21. If group X is elected, applicant must further elect one of the following sequences, SEQ ID 4 or 5

22. If group XI is elected, applicant must further elect one of the following sequences, SEQ ID 1 or 2

23. A telephone call was made to James Olesen, on May 4, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

24. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tracy Vivlemore
Examiner
Art Unit 1635

TV

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER